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# **Comparison of Caries Diagnostic Modalities: A Clinical Study in 40 Subjects**

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# Abstract

**Background and Objectives**—Few studies have been published that evaluate the usefulness of different caries-diagnostic modalities in general dental practice. The goal of this study was to compare the results of screening for coronal dental caries in a general dental practice using clinical observations, radiographs, laser fluorescence (DIAGNOdent<sup>TM</sup>) (LF), and optical coherence tomography (OCT). Diagnostic agreement between OCT and LF versus standard clinical techniques for detecting caries was determined in 40 subjects.

**Study Designs/Materials and Methods**—Forty patients with >1 coronal carious lesion as determined by prescreening using clinical examination and radiographs were enrolled in this study. Subjects with gross caries were excluded. Subsequently each patient underwent a full detailed dental examination by an experienced clinician, using visual examination and radiographs according to standard clinical practice. The coronal surfaces of a total of 932 teeth were examined and charted. Teeth were then photographed, rediagnosed using the LF system, and imaged using OCT. Two blinded pre-standardized examiners reviewed radiographic and OCT images and assigned caries status.

**Results**—Based on manufacturer's cutoff values, sensitivity and specificity for coronal caries using LF technique (i) on unaltered tooth surfaces were 73.7% and 94.1%, respectively and (ii) in previously restored or sealed teeth, they were 19.2% and 95.8%, respectively. LF technique was unable to assess tissue health underneath sealants and restorations. Clinician agreement (kappa [k]) regarding caries diagnosis using OCT imaging was overall 0.834 (SE = 0.034). Sensitivity and specificity for caries using OCT technique (i) on unaltered tooth surfaces approximated 74.1% and 95.7%, respectively and, (ii) in previously restored or sealed teeth, they approximated 76.0% and 95.6%, respectively. Although OCT was able to detect lesions beneath many resin restorations and sealants, results varied considerably between materials. OCT imaging was unable to detect caries when caries was >2 mm below the tooth surface.

**Conclusion**—These findings support the usefulness of LF for primary caries detection, and the clinical utility of OCT for early caries detection and monitoring under dental resin restorations and sealants.

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#### Keywords

dental caries; dental decay; caries detection; dental diagnosis; optical coherence tomography; laser fluorescence; decay detection; dental probing

# INTRODUCTION

In the United States, 90% of adults and 50% of children have dental caries [1,2], a condition which can lead to many complaints including toothache, dental abscesses, loss of function, poor diet, and tooth loss. Conventional means of caries detection include visual examination, tactile exploration using a dental explorer, and radiographs. Current methodology for detecting dental caries is inaccurate [3]. Visual examination is the predominant tool used by dentists. Its ability to detect the more advanced forms of caries that are associated with discoloration and cavitation is good. However, early demineralization, remineralization, and subsurface lesions are often not visible [4–6]. Another factor limiting the accuracy of visual examination is the fact that caries underneath or directly adjacent to restorations is often obscured from view, and thus remains undetected by visual inspection.

Despite its extensive use in the past, probing for surface softening is no longer advised in many clinical situations because it may exacerbate caries by damaging the integrity of enamel structure [4–6]. Although radiographs typically detect caries once it has advanced through the outer 1/3 of the enamel, they show poor sensitivity and specificity for detecting early demineralization and early caries [4,5]. Moreover, concerns about the effects of ionizing radiation lend support to the quest for alternatives to radiological examinations.

Preventive and early treatment options that permit widespread implementation of prevention interventions such as enamel remineralization and sealant placement in high-risk populations have advanced considerably in recent years; however, they are only useful if early lesions can be detected. Moreover, the widespread usage of resin-based restorative materials establishes a need for improved caries detection at restoration margins, as well as underneath a restoration. Thus, a variety of novel diagnostic approaches are under investigation. One of these is the use of laser-induced fluorescence (LF). In the most commonly used system, (DIAGNOdent<sup>™</sup>, KaVo, Biberach, Germany), the fluorescence of porphyrins associated with cariogenic bacteria resulting from exposure to red light (655 nm wavelength) is collected and quantified by the device sensor. The probe provides a numerical read-out, as well as an audible signal when caries is detected [7,8]. This device detects caries and has reportedly been used to quantify demineralization of tooth structure, including areas covered by unfilled clear dental sealants [9,10]. However, LF scores have demonstrated a weak relationship with histology [11], reportedly generating a high rate of false positives [12].

Another emergent technology is optical coherence tomography (OCT), a non-invasive, high resolution optical imaging modality that uses near-infrared light to provide high-resolution sub-surface tissue images. Conceptually, it is in many ways comparable to ultrasound scanning, except that light is used instead of sound. Broadband light waves are emitted from a source and directed toward a beam splitter, from where one wave is sent toward a reference

mirror with known path length and the other toward the tissue sample. After the two beams reflect off the reference mirror and tissue, the reflected light is directed back towards the beam splitter, where the waves are recombined and read with a photo detector. The image is produced by analyzing interference of the recombined light waves. Cross-sectional images of tissues are constructed in real time, at near histological resolution (approximately 10  $\mu$ m with current technology). With the latest technologies, 3D volume scans that can be manipulated tomographically to produce 2D pullout images in specific sites of interest have become possible [13,14]. Ex vivo studies have demonstrated that OCT can be used to detect early demineralization and incipient decay in unfilled teeth, as well as under sealants and resin restorations [15–22]. To date only a few reports have been published on the use of OCT for *in vivo* demineralization and caries detection [17–19,23].

The goal of this study was to compare the results of screening for coronal dental caries in 40 subjects in a general dental practice using clinical observations, radiographs, LF, and OCT. The specific objective of this study was to compare the accuracy for detecting coronal dental caries of LF- and OCT-based diagnosis versus the current gold standard: visual exam plus radiographs if indicated by current standards of practice.

### MATERIALS AND METHODS

#### Human Subjects, Clinical, and Imaging Procedure

This study was performed in full compliance with University of California at Irvine IRB approval #2002–2805. Forty patients (age 19–52 years, mean age of 34 years; 24 female, 16 male) with >1 coronal carious lesion as determined by a quick prescreening by one examiner using clinical examination were consented and enrolled in this study. Subjects with open cavities extending into dentin were excluded. Subsequently each patient underwent a full detailed dental examination by one experienced clinician using loupes (2.5magnification), and radiographs according to standard clinical practice. Only coronal surfaces were included in this study. Teeth were considered carious if there were white or brown spot lesions on the tooth not consistent with the clinical appearance of sound enamel. A total of 932 teeth were examined and charted. Teeth were then photographed, diagnosed using LF, and imaged using OCT. These diagnostic tools were used by the same clinician in all coronal areas of the teeth considered to be at high risk of caries: occlusal and approximal, white or brown spot lesions, non-cavitated and cavitated potential lesions, fissures, and adjacent to restorations. In addition, areas with sealants and tooth-colored restorations were assessed in order to investigate the ability of each modality to detect caries at the margins of and underneath these materials.

#### Fluorescence and Optical Coherence Tomography Diagnostic Modalities

Laser fluorescence-based diagnosis—The DIAGNOdent<sup>™</sup> system used in this study provides a numerical read-out as well as an audible signal when caries is detected. The LF unit was calibrated according to the manufacturer's instructions prior to each use. A "Zero Baseline Reading" was determined for each tooth. Each tooth was scanned with the probe by slowly rocking the wand in a pendulous motion capturing the highest reading or "the peak". Measurements were repeated until three readings were within (+/–) 3 units of each other,

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and then recorded for that surface. Diagnostic limits were set at the levels prescribed by the manufacturer.

**Optical coherence tomography**—The prototype SS-OCT system used in this study utilizes a broadband light source with an output power of 4mW at the center wavelength of  $\lambda = 1,310$  nm and bandwidth of  $\lambda = 58$  nm. The axial resolution was measured to be 14 µmin air which is in good agreement with the theoretical value of 13 µm. A small angular excursion of in the galvo-mirror was set for getting a suitable group delay scan range of approximately 2.5 mm. The corresponding carrier frequency of the interferogram was measured to be 166 kHz. A dual-balanced detector (model 1817, New Focus, Newport, CA) was employed to reduce the excess noise arising from the light source.

#### **Diagnostic Scoring**

Two blinded, pre-standardized examiners reviewed radiographic and OCT images independently and assigned caries status as either healthy or carious. Diagnostic scorers were pre-standardized to 95% accuracy after one 90-minute training session. OCT and radiographic images were scored separately as healthy/not healthy. Kappa agreement between examiners for standard-of-care diagnosis (clinical exam plus radiographs when requested) equaled 93%. During diagnostic OCT scoring, reviewers first looked at the 3D images, selected regions of interest, and then made final diagnoses based on the 2D pullout images. When scoring, the images were viewed on the computer screen at an approximate size of  $10 \times 8$  cm, based on the scorers' preferences. False scattering of up to 8 mm at an image size of  $10 \times 8$  cm was considered acceptable. The diagnosis provided by the fluorescence device was also bicategorical: either healthy or not healthy.

#### Statistical Analysis

Statistical analysis was performed to identify diagnostic agreement (kappa values) between the two scorers for the OCT images. Data were analyzed using combined results from both scorers, with "healthy" being scored if both observers scored healthy, and "not-healthy" scored if one or both observers scored "not-healthy". Sensitivities, specificities, and positive and negative predictive values were computed for the experimental diagnostic modalities. Clinical exam plus radiographs (where indicated by standard of care) were used as the diagnostic gold standard.

# RESULTS

Using these imaging, modalities added approximately 1 minute in time for each lesion examined. Both devices were easy to use, with the LF device providing instant read-ours, and the OCT images read by two pre-trained, blinded, pre-standardized examiners. Each OCT image evaluation took approximately 15 seconds. Clinician agreement (k) regarding tooth diagnosis with OCT was overall 0.834 (SE = 0.034).

An overview of the results is presented in Table 1. In 426 previously untreated teeth, a total of 51 carious and 375 healthy teeth were diagnosed using the conventional gold standard: clinical exam with a loupe and radiographs. In the 506 teeth with previous restorations or

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sealants, a total of 73 carious and 433 healthy teeth were recorded using the conventional gold standard: clinical exam with a loupe and radiographs.

On untreated tooth surfaces, LF techniques had an excellent NPV (95.7), but a less satisfactory PPV (66.7). Sensitivity and specificity were 73.7% and 94.1%, respectively. In previously restored or sealed teeth, LF techniques achieved an acceptable NPV (87.6), but PPV was low (43.8), as LF was only able to detect caries at the margins of existing restorations and not underneath sealants and restorations. Sensitivity and specificity were 19.2% and 95.8%, respectively. Using OCT imaging, the NPV for caries on unaltered tooth surfaces was excellent (95.5), but PPV was considerably lower (74.1). Sensitivity and specificity were 74.1% and 95.7%, respectively. In previously restored or sealed teeth, OCT imaging achieved an excellent NPV (95.6) but again PPV was less satisfactory (76.0). Sensitivity and specificity were 74.0% and 96.0%, respectively. Although OCT imaging was able to detect lesions beneath many resin restorations and sealants, results varied considerably between materials. Caries was not detected from OCT images when caries was >2 mm below the tooth surface.

# DISCUSSION

The purpose of this study was to investigate multiple approaches to caries detection in general dental practice. In this setting, accuracy, as well as ease and speed of use are important factors, as is cost. With the emergence of new prevention interventions for early caries, and evolving treatment options for more advanced caries, evaluations of various caries-diagnostic technologies can provide important guidance to clinicians as they select cost-effective state-of-the art tools for their clinical practice.

Visual examination alone provides limited diagnostic accuracy, especially in regions that are difficult to view, such as interproximal areas [3–6]. Monitoring de- and remineralization with the naked eye is challenging at best [4–6]. Clinical examinations that use probing can damage the tooth surface, potentially exacerbating early lesions. This technique is also not very sensitive to de- and remineralization processes [4–6]. Radiographs have been used for many years as an important diagnostic aide in general dental practice, providing a considerable amount of valuable diagnostic information. Again, very early caries is often not visible, and structural overlap in the 2D images can reduce diagnostic accuracy [4,5]. Radiation exposure is another disadvantage.

LF techniques are attractive to clinicians because the device is easy to use, small, compact, and relatively inexpensive. The most notable inconvenience in using the device is the need for repeated recalibration. In this study, radiographs—and to some extent OCT—detected subsurface lesions not recognized by LF. Caries detection under sealants or restorations was not possible using LF, and diagnostic performance at the borders of existing restorations was also poor. Conversely, LF imaging registered more lesions than any other modality. This means that either LF was diagnosing lesions in areas where none actually existed, or that the other modalities were unsuccessful in detecting existing pathologies.

OCT devices are far more costly than an LF device, relatively large, heavy, and cumbersome. Clinicians typically require several hours before they are able to use the device routinely and confidently. Existing commercial devices do not contain a caries-diagnostic algorithm, requiring a visual "read" of each image. However, many OCT devices have the ability to image three-dimensionally, so that lesions can be mapped accurately in 3D and examined from all aspects. Moreover, as previous studies have demonstrated that OCT techniques can be used to accurately detect caries, de- and remineralization by means of differing optical intensities in the image [15–20], it should be possible to develop diagnostic algorithms in the future. In addition, this study confirmed the results of previous investigations demonstrating the ability of OCT imaging to detect caries underneath sealants and resin restorations to a depth of approximately 2 mm [18,21–23].

# CONCLUSION

In summary, LF and OCT techniques can provide useful diagnostic information in a clinical dental setting, with OCT potentially providing a good alternative to radiographs. LF techniques performed best on surface lesions, but were only able to detect caries at the margins of existing restorations and not underneath sealants and restorations. Using OCT imaging, surface lesions, as well as lesions in previously restored or sealed teeth, were identified. Although OCT imaging was able to detect lesions beneath many resin restorations and sealants, results varied considerably between materials. Caries was not detected from OCT images when caries was >2 mm below the tooth surface. Additional studies are necessary to further define the performance of OCT in the clinical setting, and simple diagnostic algorithms are required to simplify image interpretation.

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# TABLE 1

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	LF (untreated teeth) (%)	LF <sup>*</sup> (teeth with restorations) (%)	L.F <sup>*</sup> (teeth with sealants (%)	LF* (previously restored or sealed teeth) (%)	OCT (untreated teeth) (%)	OCT (teeth with restorations) (%)	OCT (teeth with sealants) (%)	OCT (previously restored or sealed teeth) (%)
PPV	66.7	29.7	49.8	43.8	74.1	74.9	81.2	76.0
NPV	95.7	64.2.	89.6	87.6	95.5	94.4	96.2	95.6
Specificity	94.1	94.3	96.2	95.8	95.7	95.1	96.3	96.0
Sensitivity	73.7	11.9	21.2	19.2	74.1	72.3	74.7	74.0
False negatives	3.5 $(n = 15)$	11.4 (n = 46)	12.5 (n = 13)	11.7 (n = 59)	3.8 (n = 16)	4.2 (n = 17)	2.0 (n = 2)	3.8 (n = 19)
False positives	4.9 (n = 21)	2.7 (n = 14)	3.8 (n = 4)	3.6 (n = 18)	3.5 (n = 15)	3.7 (n = 15)	2.0 (n = 2)	3.4 (n = 17)

LF was only able to assess the status of the margins of restorations and sealants, not the status of underlying tooth substance.